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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/31/2003

Farid Bruce Khalili

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/696,846	Applicant(s) KHALILI, FARID BRUCE	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 8-10 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 8-10 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the new limitation that the base portions have at least one inverted frustocone was not found in the written disclosure. Additionally, there is no description that the frustocone is located in the center or two frustocones are positioned concentrically. Because there is no description as to what element Applicant is meaning to claim, the disclosure is interpreted with the understood meaning of frustoconical as cone shaped that is truncated.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2,3,8-10,17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 17 recites that each of the base components have a side having at least two teeth and an inverted frustocone.

While the drawings may show there are at least three vertebral engaging elements in the form of teeth on the outer surface of a base member, the new limitation introduces a new concept, that the teeth can be different than one another. Note, the Examiner understands the teeth to be "frustocones" since they are inverted and truncated. The drawings provide no support for teeth being of different shape and the written disclosure describes no difference between teeth. The new limitation is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2,3, 8-10,17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites the limitation "the concave portion" in line 10 of the claim. There is insufficient antecedent basis for this limitation in the claim. The concave portion of what? The remaining claims depend from claim 17.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2,3,8,10,17 are rejected as best understood under 35 U.S.C. 103(a) as being unpatentable over Mazda (WO 94/04100) in view of Khandkar et al. (2004/133281). Mazda shows (Fig. 5) a spinal implant with a top base component **25**, a bottom base component **26**, and a middle component **22** having a convex side **9**. The top component has a component having a concave portion **12** with a constant radius to engage the convex surface of the middle component. Regarding claim 8, it can be seen the middle component is removably or slidably received in slot **28** the convex portion extends above the "generally" flat portion of the inner side of the bottom component. It can be construed that grooves in the plates for the screw in teeth lie below the flat surface and surround the convex component. As seen in Fig. 5, there are at least three teeth **17** and are positioned on each side of the top and bottom components for **engaging** vertebrae with the teeth being conical. However, Mazda fails to disclose the teeth are frustocones. Khandkar et al. teach (Figs. 1,2) that there are at least three frustoconical teeth **16** on the top and bottom components of a spinal implant. It would have been obvious to one of ordinary skill in the art to modify the teeth of the spinal implant of Mazda and use frustocone shapes for them as taught by Khandkar et al. since such a modification only involves routine skill in the art and has predictable results from the change in shape. Regarding claim 10, Mazda fails to disclose the middle component varies in height from posterior to anterior edges. Khandkar et al. teach (Fig. 8) that middle component **42** varies in height from posterior to anterior edges to provide limited amount of axial rotation and translation, Paragraph 73. It would have been obvious to one of ordinary skill in the art to modify the middle component to be varied in

height as taught by Khandkar et al. in the spinal implant of Mazda such that it limits movement in a patient that can only have limited motion.

Claims 2,3,8,9,17 are rejected as best understood under 35 U.S.C. 103(a) as being unpatentable over Boyd et al. (5425773). Boyd et al. show (Fig. 6) a spinal implant with a top component, a bottom component, and a middle component **146** having a convex side. The top component has a component having a concave portion **126** to engage the convex surface of the middle component. Regarding claim 8, it can be seen the middle component is removably or slidably received in a groove that surrounds it and is in the inner side of the bottom component and the convex portion extends above a flat portion of the wall outer perimeter of the groove. It can also be construed (as best understood) that the side of the top component **engaging** vertebrae has teeth **92** that are conical. With respect to claim 9, Fig. 7 shows a spinal implant with the middle component having a convex portion having a center of radius that is closer to an anterior edge than a posterior edge. However, Boyd et al. fail to disclose the teeth are frustocones. Khandkar et al. teach (Figs. 1,2) that there are at least three frustoconical teeth **16** on the top and bottom components of a spinal implant. It would have been obvious to one of ordinary skill in the art to modify the teeth of the spinal implant of Boyd et al. and use frustcone shapes for them as taught by Khandkar et al. since such a modification only involves routine skill in the art and has predictable results from the change in shape.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazda (WO 94/04100) in view of Khandkar et al. (2004/133281) as applied to claim17 above,

and further in view of Krueger et al. (2004/143332). Mazda in view of Khandkar et al. is explained above. However, Mazda as modified by Khandkar fail to disclose the frustocone in the central area of the base components. It is noted that Mazda and Khandkar disclose teeth on perimeter areas of the base components. Krueger et al. teach (Fig. 24) that teeth anchoring structures are located at both periphery and central areas of base components of spinal implants. It would have been obvious to one of ordinary skill in the art to use the teaching of Krueger et al. to place anchoring structure in both the **periphery** and central **area** of base components for the spinal implant of Mazda as modified by Khandkar et al. such that it more securely attaches the implant to the vertebrae and no region is unsecured.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazda in view of Khandkar et al. and Krueger et al. as applied to claim 18 above, and further in view of Alfaro et al. (2001/32017). Mazda as modified by Khandkar and Krueger is explained supra. However, Mazda in view of Khandkar and Krueger fail to disclose concentric structure. Alfaro et al. teach (Figs. 1,6A,11) that bone engaging structure centrally located can be concentric and conical in dimension since it is stepped to match contour of vertebral endplates, paragraph 11. It would have been obvious to one of ordinary skill in the art to incorporate a stepped concentric central section as taught by Alfaro et al. with the spinal implant of Mazda as modified by Khandkar et al. and Krueger et al. such that it conforms to the vertebral bodies the prosthesis is implanted therein.

Response to Arguments

Applicant's arguments with respect to claims 2,3,8-10,17 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 7/25/07 have been fully considered but they are not persuasive. Applicant argued that Mazda had teeth on the implant and did not argue that Boyd failed to teach teeth also, but that the prior art did not teach a frustocone structure. Since the term is broad word and only imparts shape, the Examiner as best understood has applied art with structure being frustoconical.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738